LATHAM & WATKINS LLP

August 20, 2021

VIA ECF

Hon. Philip M. Halpern United States District Judge Southern District of New York 500 Pearl Street, Room 1950 New York, New York 10007 555 Eleventh Street, N.W., Suite 1000 Washington, D.C. 20004-1304 Tel: +1.202.637.2200 Fax: +1.202.637.2201

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Re: Allele Biotechnology and Pharmaceuticals, Inc. v. Regeneron <u>Pharmaceuticals Inc.</u>, Case No. 7:20-cv-08255 (PMH) (AEK) (S.D.N.Y.)

Dear Judge Halpern:

Pursuant to the Court's Order during the June 15, 2021 Pre-Motion Conference, the parties jointly submit the following status report on the limited discovery ordered by the Court.

During the June 15, 2021 conference, the Court granted Regeneron leave to file its Motion to Dismiss, and the parties leave to conduct limited discovery. *See* June 15, 2021 Minute Entry. The Court instructed the parties to meet and confer regarding the allegations in the First Amended Complaint of post-approval uses and uses unrelated to FDA submission of the fluorescent protein mNeonGreen in connection with Regeneron's REGEN-COV antibody cocktail and to work collaboratively to engage in discovery limited to those issues. *Id.* That limited discovery was to be completed by August 20, 2021, at which time the parties were to provide a joint update to the Court regarding the same. *Id.*

Since the June 15, 2021 conference, the parties have been working collaboratively to complete the specified discovery. The parties met and conferred on June 23, 2021, and Regeneron offered to provide Allele a proposed declaration stating that Regeneron has ceased all use of mNeonGreen, will not use it in the future, and has not used it with its REGEN-COV antibody cocktail for any purpose unrelated to FDA submission.

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On July 22, 2021, Regeneron provided Allele with a draft declaration and supporting documentation. On July 28, 2021, following Allele's review of Regeneron's draft declaration, it provided a list of additional inquiries and requests to Regeneron, including questions regarding any potential uses of mNeonGreen unrelated to the REGEN-COV product. Regeneron responded on July 29, 2021, and agreed to consider and investigate Allele's requests. On August 4, 2021, Regeneron provided a response to certain of Allele's inquiries, objected to certain inquiries, and indicated that it was continuing to investigate others, and would provide a revised version of the declaration. Regeneron asserted that uses of mNeonGreen for projects other than REGEN-COV were beyond the scope of the allegations in Allele's First Amended Complaint and the anticipated scope of this limited discovery. Allele disagreed with that assessment. In the interest of compromise, Regeneron agreed to try to address this inquiry through an amended declaration. On August 18, 2021, Regeneron provided Allele with a revised version of the declaration. Allele is currently evaluating the revised declaration, but has not yet had sufficient time to determine whether additional discovery will be required. The parties are working together in good faith to resolve any outstanding issues, but they are not yet in a position to agree that the limited discovery process has resolved all outstanding issues.

Respectfully submitted,

/s/ Michael A. Morin_

Michael A. Morin (pro hac vice) of LATHAM & WATKINS LLP

cc: All Counsel of Record (via ECF)